K080248

510(k) Summary for the
Lutronic Corporation Spectra VRMIII Laser System

APR 23 2008

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: Lutronic Corporation
#403-2,3,4, Ilsan Technotown
1141-1 Baeksok-Dong, Ilsan-Gu
Goyang-Si, Gyconggi-Do, 410-722
Republic of Korea

Contact Person: Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Telephone: 978-207-1245
Fax: 978-824-2541

Summary Preparation Date: April 16, 2008

2. Names

Device Name: Spectra VRMIII Laser System

Classification Name: Laser Instrument, Surgical, Powered
Product Code: GEX
Panel: General & Plastic Surgery

3. Predicate Devices

The Spectra VRMIII Laser System is substantially equivalent to the Lutronic Corporation Spectra VRMII Q-Switched Nd:YAG Laser System, the HOYA ConBio MedLite C6 Laser System and the RevLite Laser System.

4. Device Description

The Spectra VRMIII Laser System produces a pulsed beam of coherent near infrared (1064 nm) and visible (532nm) light. This beam is directed to the treatment zone by means of an articulated arm coupled to a handpiece. In addition, two dye handpieces are available that convert the 532 nm wavelength to 585 nm and 650 nm.

When the beam contacts human tissue, the energy in the beam is absorbed, resulting in a very rapid, highly localized temperature increase to the target chromospheres such as melanin and tattoo particles. This increases localized temperature of the chromospheres. The instantaneous temperature increase causes fragmentation of the chromospheres to smaller particles.

By directing the beam onto specific tissue locations, using different handpieces, and controlling the treatment fluence, the intensity of the temperature of the target can be varied. The physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam.

5. Indications for Use

The Spectra VRMIII Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

- 532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):
  - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
  - Removal of Epidermal Pigmented Lesions
  - Removal of Minor Vascular Lesions including but not limited to telangiectasias
  - Treatment of Lentigines
  - Treatment of Café-Au-Lait
  - Treatment of Seborrheic Keratoses
  - Treatment of Post Inflammatory Hyper-Pigmentation
  - Treatment of Becker's Nevi, Freckles and Nevi Spilus

- 1064nm Wavelength:
  - Tattoo removal: dark ink (black, blue and brown)
  - Removal of Nevus of Ota
  - Removal or lightening of unwanted hair with or without adjuvant preparation.
  - Treatment of Common Nevi
  - Skin resurfacing procedures for the treatment of acne scars and wrinkles

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

Lutronic Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
Regulatory Consultant
5 Timber Lane
North Reading, Massachusetts 01864

Re: K080248
Trade/Device Name: Spectra VRMIII
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 11, 2008
Received: March 12, 2008

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080248

Device Name: Spectra VRMIII

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Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K080248